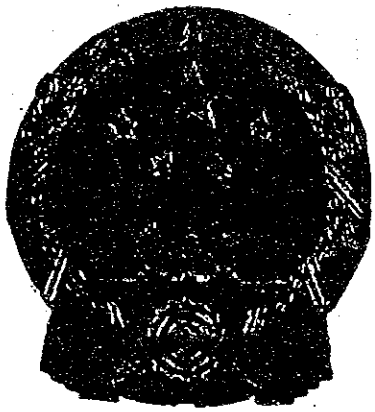
6. 中華人民共和国薬品管理法（中華人民共和国薬品管理法）



中华人民共和国药品管理法

THE DRUG ADMINISTRATION LAW OF THE PEOPLE'S REPUBLIC OF CHINA

1984

中华人民共和国药品管理法

一九八四年九月二十日第六届全国人民
代表大会常务委员会第七次会议通过

中华人民共和国卫生部

中华人民共和国主席令

第十八号

《中华人民共和国药品管理法》已由中华人民共和国第六届全国人民代表大会常务委员会第七次会议于一九八四年九月二十日通过，现予公布，自一九八五年七月一日起施行。

中华人民共和国主席　李先念

一九八四年九月二十日

中华人民共和国药品管理法

一九八四年九月二十日第六届全国人民代表大会
常务委员会第七次会议通过

第一章 总 则

第一条 为加强药品监督管理，保证药品质量，增进药品疗效，保障人民用药安全，维护人民身体健康，特制定本法。

第二条 国务院卫生行政部门主管全国药品监督管理工作。

第三条 国家发展现代药和传统药，充分发挥其在预防、医疗和保健中的作用。

国家保护野生药材资源，鼓励培育中药材。

第二章　药品生产企业的管理

第四条　开办药品生产企业必须由所在省、自治区、直辖市药品生产经营主管部门审查同意，经所在省、自治区、直辖市卫生行政部门审核批准，并发给《药品生产企业许可证》。无《药品生产企业许可证》的，工商行政管理部门不得发给《营业执照》。

《药品生产企业许可证》应当规定有效期，到期重新审查发证。具体办法由国务院卫生行政部门规定。

第五条　开办药品生产企业必须具备以下条件：

一、具有与所生产药品相适应的药师或者助理工程师以上技术人员及技术工人。

中药饮片加工企业没有药师或者助理工程师以上技术人员的，配备熟悉药性并经县级以上卫生行政部门审查登记的药工人员。

二、具有与所生产药品相适应的厂房、设施和卫生环境。

三、具有能对所生产药品进行质量检验的机构或者人员以及必要的仪器设备。

第六条 药品必须按照工艺规程进行生产，生产记录必须完整准确。

中药饮片的炮制，必须符合《中华人民共和国药典》或者省、自治区、直辖市卫生行政部门制定的《炮制规范》的规定。

第七条 生产药品所需的原料、辅料以及直接接触药品的容器和包装材料，必须符合药用要求。

第八条 药品出厂前必须经过质量检验；不符合标准的，不得出厂。

第九条 药品生产企业必须按照国务院卫生行政部门制定的《药品生产质量管理规范》的要求，制定和执行保证药品质量的规章制度和卫生要求。

第三章 药品经营企业的管理

第十条 开办药品经营企业必须由所在地药品生产经营主管部门审查同意，经县级以上卫生行政部门审核批准，并发给《药品经营企业许可证》。无《药品经营企业许可证》的，工商行政管理部门不得发给《营业执照》。

《药品经营企业许可证》应当规定有效期，到期重新审查发证。具体办法由国务院卫生行政部门规定。

第十一条 开办药品经营企业必须具备以下条件：

一、具有与所经营药品相适应的药学技术人员。

经营中药的企业和兼营药品的企业没有药学技术人员的，配备熟悉所经营药品的药性并经县级以上卫生行政部门审查登记的药工人员。

二、具有与所经营药品相适应的营业场所、设备、仓储设施和卫生环境。

第十二条 收购药品，必须进行质量验收；不合格的，不得收购。

第十三条 销售药品必须准确无误，并正确说明用法、用量和注意事项；调配处方必须经过核对，对处方所列药品不得擅自更改或者代用。对有配伍禁忌或者超剂量的处方，应当拒绝调配；必要时，经处方医生更正或者重新签字，方可调配。

销售地道中药材，必须标明产地。

第十四条 药品仓库必须制定和执行药品保管制度，采取必要的冷藏、防潮、防虫、防鼠等措

施。

药品入库和出库必须执行检查制度。

第十五条 城乡集市贸易市场可以出售中药材，国家另有规定的除外。

城乡集市贸易市场不得出售中药材以外的药品，持有《药品经营企业许可证》的除外。

第四章 医疗单位的药剂管理

第十六条 医疗单位必须配备与其医疗任务相适应的药学技术人员，非药学技术人员不得直接从事药剂技术工作。

第十七条 医疗单位配制制剂必须经所在省、自治区、直辖市卫生行政部门审查批准，并发给《制剂许可证》。

《制剂许可证》应当规定有效期，到期重新审查发证。具体办法由国务院卫生行政部门规定。

第十八条 医疗单位配制制剂必须具有能够保证制剂质量的设施、检验仪器和卫生条件。

第十九条 医疗单位配制的制剂，必须根据临床需要并按照规定进行质量检验；合格的，凭医生处方使用。

医疗单位配制的制剂，不得在市场销售。

第二十条 医疗单位购进药品，必须执行质量验收制度。

第五章 药品的管理

第二十一条 国家鼓励研究、创制新药。

研制新药，必须按照规定向国务院卫生行政部门或者省、自治区、直辖市卫生行政部门报送研制方法、质量指标、药理及毒理试验结果等有关资料和样品，经批准后，方可进行临床试验或者临床验证。

完成临床试验或者临床验证并通过鉴定的新药，由国务院卫生行政部门批准，发给证书。

第二十二条 生产新药，必须经国务院卫生行政部门批准，并发给批准文号。但是，生产中药饮片除外。

生产已有国家标准或者省、自治区、直辖市标准的药品，必须经省、自治区、直辖市卫生行政部门征求同级药品生产经营主管部门意见后审核批准，并发给批准文号。但是，生产中药饮片除外。

第二十三条 药品必须符合国家药品标准或者省、自治区、直辖市药品标准。

国务院卫生行政部门颁布的《中华人民共和国药典》和药品标准为国家药品标准。

国务院卫生行政部门的药典委员会，负责组织国家药品标准的制定和修订。

第二十四条 国务院卫生行政部门和省、自治

区、直辖市卫生行政部门可以成立药品审评委员会，对新药进行审评，对已经生产的药品进行再评价。

第二十五条 国务院卫生行政部门对已经批准生产的药品，应当组织调查；对疗效不确、不良反应大或者其他原因危害人民健康的药品，应当撤销其批准文号。

已被撤销批准文号的药品，不得继续生产、销售；已经生产的，由当地卫生行政部门监督销毁或者处理。

第二十六条 禁止进口疗效不确、不良反应大或者其他原因危害人民健康的药品。

第二十七条 首次进口的药品，进口单位必须提供该药品的说明书、质量标准、检验方法等有关资料和样品以及出口国(地区)批准生产的证明文件，经国务院卫生行政部门批准，方可签订进口合同。

第二十八条 进口的药品，必须经国务院卫生

行政部门授权的药品检验机构检验；检验合格的，方准进口。

医疗单位临床急需或者个人自用进口的少量药品，按照海关的规定办理进口手续。

第二十九条 对国内供应不足的中药材、中成药，国务院卫生行政部门有权限制或者禁止出口。

第三十条 进口、出口麻醉药品和国务院卫生行政部门规定范围内的精神药品，必须持有国务院卫生行政部门发给的《进口准许证》、《出口准许证》。

第三十一条 新发现和从国外引种的药材，经省、自治区、直辖市卫生行政部门审核批准后，方可销售。

第三十二条 地区性民间习用药材的具体管理办法，由国务院卫生行政部门制定。

第三十三条 禁止生产、销售假药。有下列情形之一的为假药：

一、药品所含成份的名称与国家药品标准或者省、自治区、直辖市药品标准规定不符合的。

二、以非药品冒充药品或者以他种药品冒充此种药品的。

有下列情形之一的药品按假药处理：

一、国务院卫生行政部门规定禁止使用的。

二、未取得批准文号生产的。

三、变质不能药用的。

四、被污染不能药用的。

第三十四条 禁止生产、销售劣药。有下列情形之一的药品为劣药：

一、药品成份的含量与国家药品标准或者省、自治区、直辖市药品标准规定不符合的。

二、超过有效期的。

三、其他不符合药品标准规定的。

第三十五条 药品生产企业、药品经营企业和医疗单位直接接触药品的工作人员，必须每年进行健康检查。患有传染病或者其他可能污染药品的疾病的患者，不得从事直接接触药品的工作。

第六章 药品的包装和分装

第三十六条 药品包装必须适合药品质量的要求，方便储存、运输和医疗使用。规定有效期的药品，必须在包装上注明有效期。

发运中药材必须有包装。在每件包装上，必须注明品名、产地、日期、调出单位，并附有质量合格的标志。

第三十七条 药品包装必须按照规定贴有标签并附有说明书。

标签或者说明书上必须注明药品的品名、规格、生产企业、批准文号、产品批号、主要成份、适应症、用法、用量、禁忌、不良反应和注意事项。

麻醉药品、精神药品、毒性药品、放射性药品和外用药品的标签，必须印有规定的标志。

第三十八条 药品经营企业分装药品，必须具有与所分装药品相适应的设施和卫生条件，由药学技术人员负责，分装记录必须完整准确。

分装药品必须附有说明书，在包装上注明品名、规格、生产企业和产品批号、分装单位和分装批号。规定有效期的药品，分装后必须注明有效期。

第七章　特殊管理的药品

第三十九条　国家对麻醉药品、精神药品、毒性药品、放射性药品，实行特殊的管理办法。管理办法由国务院制定。

第四十条　麻醉药品，包括原植物，只准由国务院卫生行政部门会同有关部门指定的单位生产，并由省、自治区、直辖市卫生行政部门会同有关部门指定的单位按照规定供应。

第八章　药品商标和广告的管理

第四十一条　除中药材、中药饮片外，药品必须使用注册商标；未经核准注册的，不得在市场销售。

注册商标必须在药品包装和标签上注明。

第四十二条 药品广告必须经省、自治区、直辖市卫生行政部门审查批准；未经批准的，不得刊登、播放、散发和张贴。

第四十三条 外国企业在我国申请办理药品广告，必须提供生产该药品的国家（地区）批准的证明文件、药品说明书和有关资料。

第四十四条 药品广告的内容必须以国务院卫生行政部门或者省、自治区、直辖市卫生行政部门批准的说明书为准。

第九章 药品监督

第四十五条 县级以上卫生行政部门行使药品监督职权。

县级以上卫生行政部门可以设置药政机构和药品检验机构。

第四十六条 县级以上卫生行政部门设药品监

督员。药品监督员由药学技术人员担任，由同级人民政府审核发给证书。

第四十七条 药品监督员有权按照规定对辖区内的药品生产企业、药品经营企业和医疗单位的药品质量进行监督、检查、抽验，必要时可以按照规定抽取样品和索取有关资料，有关单位不得拒绝和隐瞒。药品监督员对药品生产企业和科研单位提供的技术资料，负责保密。

第四十八条 药品生产企业、药品经营企业和医疗单位，应当经常考察本单位所生产、经营、使用的药品的质量、疗效和不良反应。

医疗单位发现药品中毒事故，必须及时向当地卫生行政部门报告。

第四十九条 药品生产企业和药品经营企业的药品检验机构或者人员，受当地药品检验机构的业务指导。

第十章　法律责任

第五十条　生产、销售假药的，没收假药和违法所得，处以罚款，并可以责令该单位停产、停业整顿或者吊销《药品生产企业许可证》、《药品经营企业许可证》、《制剂许可证》。

对生产、销售假药，危害人民健康的个人或者单位直接责任人员，依照刑法第一百六十四条的规定追究刑事责任。

第五十一条　生产、销售劣药的，没收劣药和违法所得，可以并处罚款；情节严重的，并责令该单位停产、停业整顿或者吊销《药品生产企业许可证》、《药品经营企业许可证》、《制剂许可证》。

对生产、销售劣药，危害人民健康，造成严重后果的个人或者单位直接责任人员，比照刑法第一

百六十四条的规定追究刑事责任。

第五十二条 未取得《药品生产企业许可证》、《药品经营企业许可证》、《制剂许可证》生产药品、经营药品或者配制制剂的，责令该单位停产、停业或者停止配制制剂，没收全部药品和违法所得，可以并处罚款。

第五十三条 违反本法关于药品生产、药品经营的管理的其他规定的，处以警告或者罚款。

第五十四条 本法规定的行政处罚，由县级以上卫生行政部门决定。违反本法第十五条规定、第八章有关广告管理的规定的行政处罚，由工商行政管理部门决定。

对中央或者省、自治区、直辖市人民政府直接管辖的药品生产企业、药品经营企业处以停产、停业整顿七天以上或者吊销《药品生产企业许可证》、《药品经营企业许可证》处罚的，由省、自治区、

直辖市卫生行政部门报同级人民政府决定。对市、县或者市、县以下人民政府管辖的药品生产企业、药品经营企业处以停产、停业整顿七天以上或者吊销《药品生产企业许可证》、《药品经营企业许可证》处罚的，由市、县人民政府卫生行政部门报同级人民政府决定。

没收的药品，由卫生行政部门监督处理。

第五十五条 当事人对行政处罚决定不服的，可以在接到处罚通知之日起十五天内向人民法院起诉。但是，对卫生行政部门作出的药品控制的决定，当事人必须立即执行。对处罚决定不履行逾期又不起诉的，由作出行政处罚决定的机关申请人民法院强制执行。

第五十六条 违反本法，造成药品中毒事故的，致害单位或者个人应当负损害赔偿责任。受害人可以请求县级以上卫生行政部门处理；当事人不服的，

可以向人民法院起诉。受害人也可以直接向人民法院起诉。

损害赔偿要求，应当从受害人或者其代理人知道或者应当知道之日起一年内提出；超过期限的，不予受理。

第十一章 附 则

第五十七条 本法下列用语的含义是：

药品：指用于预防、治疗、诊断人的疾病，有目的地调节人的生理机能并规定有适应症、用法和用量的物质，包括中药材、中药饮片、中成药、化学原料药及其制剂、抗生素、生化药品、放射性药品、血清疫苗、血液制品和诊断药品等。

新药：指我国未生产过的药品。

辅料：指生产药品和调配处方时所用的赋形剂

和附加剂。

药品生产企业：指生产药品的专营企业或者兼营企业。

药品经营企业：指经营药品的专营企业或者兼营企业。

第五十八条 本法所说的药品生产，不包括中药材的种植、采集和饲养。

第五十九条 国务院卫生行政部门根据本法制定实施办法报国务院批准施行。

中国人民解放军特需药品的管理办法，由国家军事主管部门制定。

第六十条 本法自一九八五年七月一日起施行。

附：

《药品管理法》引用的刑法有关条文

第一百六十四条，以营利为目的，制造、贩卖

假药危害人民健康的，处二年以下有期徒刑、拘役或者管制，可以并处或者单处罚金；造成严重后果的，处二年以上七年以下有期徒刑，可以并处罚金。

THE DRUG ADMINISTRATION LAW OF THE PEOPLE'S REPUBLIC OF CHINA

ADOPTED AT THE SEVENTH SESSION
OF THE STANDING COMMITTEE
OF THE SIXTH NATIONAL
PEOPLE'S CONGRESS ON
SEPTEMBER 20, 1984

Ministry of Public Health
The People's Republic of China

The order of the president of the People's Republic of China

NO. 18

The Drug Administration Law of the People's Republic of China was adopted on September 20, 1984 at the 7th session of the Standing Committee of the 6th National People's Congress, and it is now formally announced. This Law shall enter into force on July 1, 1985.

President of the People's
Republic of China LI XIAN-NIAN

September 20, 1984

THE DRUG ADMINISTRATION LAW OF THE PEOPLE'S REPUBLIC OF CHINA

ADOPTED AT THE SEVENTH SESSION OF THE STANDING COMMITTEE OF THE SIXTH NATIONAL PEOPLE'S CONGRESS ON SEPTEMBER 20, 1984

CHAPTER I
GENERAL PROVISIONS

Article 1 This law is enacted to strengthen the supervision and management of drugs, guarantee the quality of drugs, improve the efficacy of drugs, assure the safety of drug administration and safeguard the health of the people.

Article 2 The Ministry of Public Health is responsible for the national supervision and management of drugs.

Article 3 The State encourages the development of both modern and traditional drugs, the role of which in the prevention and treatment of diseases as well as in health care will be fully brought into play.

The State protects the resources of wild herbal drugs and encourages domestic cultivation of herbal drugs.

CHAPTER 1
THE CONTROL OF DRUG MANUFACTURING ENTERPRISES

Article 4 The establishment of a drug manufacturing enterprise must be approved by the competent authorities in charge of the production and management of drugs of the relevant province, autonomous region or municipality, and sanctioned by its health administrative agency. A "drug manufacturer certificate" will be issued by the health administrative agency. Without the certificate, no"business license"will be granted by the local industrial and commercial management agency.

A date of expiration should be fixed for each "drug manufacturer certificate" , and an application for the renewal of a certificate should be submitted before it expires. Relevant regulations of the certification procedure will be stipulated by the Ministry of Public Health.

Article 5 A drug manufacturing enterprise should be established on the following basis:

1) It should be staffed with an adequate number of pharmacists or technical personnel with a title equivalent to or higher than associate engineer, and skilled workers adaptable

to the scale of drug production.

Enterprises for the preparing and slicing of herbal drugs should be staffed with pharmaceutical professionals familiar with the property of drugs and registered with the health bureau above the county level, if pharmacists or technical personnel with a title equivalent to or higher than associate engineer are not available.

2) It should have adequate premises and equipment adaptable to the scale of drug production, as well as a suitable hygienic environment.

3) It should have a department or a group of qualified analysts equipped with necessary instruments to examine the quality of drugs.

Article 6 Drug must be manufactured pursuant to the provisions prescribed in the technological manual, and the data of production should be recorded completely and accurately.

Herbal drugs must be prepared and sliced in compliance with the specifications of the "Pharmacopoeia of the People's Republic of China" or the processing norms stipulated by the health bureau of province, autonomous region or municipality.

Article 7 Raw materials and excipients used in drug production and the containers and packaging materials in direct contact with drugs should be of a grade suitable for pharmaceutical purposes.

Article 8 Drugs should not be dispatched from the factory before their quality examination has been completed or if they are found to be substandard.

Article 9 Drug manufacturing enterprises must stipulate and implement the rules, regulations and hygienic requirements in accordance with the instructions set forth in the "Norms of Quality Control in Drug Production" by the Ministry of Public Health so as to guarantee the quality of drugs.

CHAPTER Ⅱ
THE CONTROL OF DRUG HANDLING ENTERPRISES

Article 10 The establishment of a drug handling enterprise must be approved by the competent authorities in charge of the production and management of drugs of the relevant province, autonomous region or municipality, and sanctioned by the health bureau above the county level. A "drug handler certificate" will then be issued. Without this certificate, no "business license" will be granted by the industrial and commercial management agency.

A date of expiration should be fixed for each "drug handler certificate", and an application for the renewal of a certificate should be submitted before it expires. Relevant regulations of the certification procedure will be stipulated by the Ministry of Public Health.

Article 11 A drug handling enterprise should be established on the following basis:

1) It should be staffed with an adequate number of pharmaceutical technicians adaptable to the scale of its business.

Enterprises engaged in the handling of herbal drugs or partly engaged in the handling of drugs may be staffed with pharmaceutical professionals familiar with the property of drugs and registered with the health bureau above the county level if pharmaceutical technicians are not available.

2) It should have adequate premises, and equipment and storing facilities adaptable to the scale of its business, as well as a hygienic environment.

Article 12 The quality of drugs should be examined on purchasing; substandard products should not be bought.

Article 13 Care should be taken to avoid mistakes in the sale of drugs. The usage, dosage and precautions should be properly stated. Drugs dispensed for any prescription should be checked for any discrepancies, and no ingredient of any prescription should be altered or substituted. Incompatible or over-dosaged prescriptions should be refused, unless amendments have been made by the prescriber or re-signed by him.

Genuine herbal drugs on sale should be labelled with their origin.

Article 14 Drug warehouses must stipulate and imple-

ment the rules and regulations for the preservation of drugs, and measures should be taken to control the temperature and humidity, and to avoid insects and rodents.

An inspection system should be implemented when drugs are added to or cleared from the stock.

Article 15 The sale of herbal drugs on the market of country fairs is permitted with certain exceptions.

The sale of drugs other than herbal drugs on the market of country fairs is prohibited unless the dealer is the holder of a "drug handler certificate".

GHAPTER Ⅳ
DRUG CONTROL IN MEDICAL UNITS

Article 16 Medical units should be staffed with pharmaceutical technicians adaptable to their speciality, and non-pharmaceutical personnel should not be directly engaged in pharmaceutical work.

Article 17 The dispensing of pharmaceutical preparations in medical units should be sanctioned by the health bureau of relevant province, autonomous region or municipality. A "drug dispensing certificate" will be issued on approval. A date of expiration should be fixed for each "drug dispensing certificate", and an application for the renewal of

a certificate should be submitted before it expires. Relevant regulations of the certification procedure will be stipulated by the Ministry of Public Health.

Article 18 In order to guarantee the quality of drugs, any medical unit dispensing pharmaceutical preparations should be adequately equipped with dispensing facilities and analytical instruments, and a suitable hygienic environment.

Article 19 Pharmaceutical preparations dispensed by medical units should be examined on the basis of clinical necessity and established standards, can only be used when they are up to standard and prescribed by a doctor.

Pharmaceutical preparations dispensed by medical units should not be sold on the market.

Article 20 The quality of drugs purchased by medical units should be examined upon receiving.

CHAPTER V
THE CONTROL OF DRUGS

Article 21 The State encourages the research and development of new drugs.

The clinical trial or clinical verification of a new drug should be sanctioned by the Ministry of Public Health or the health bureau of province, autonomous region or municipality. An application for the clinical trial of a new drug

should be accompanied with relevant information such as the method of production, the criteria of its quality, and the results of pharmacological and toxicological tests, and a sample of specified size.

A new drug will be approved for clinical use and a license issued by the Ministry of Public Health if the clinical trial or clinical verification has been completed and an appraisal of its efficacy has been made.

Article 22 With the exception of prepared slice of herbal drugs, the production of new drugs can only be carried out when an approval document with an approval number has been issued by the Ministry of Public Health.

With the exception of prepared slice of herbal drugs, the production of drugs for which a national, provincial, autonomous regional or municipal standard has been established can only be carried out when an approval document with an approval number has been given by the health bureau of province, autonomous region or municipality with the concurrence of the competent authorities in charge of the production and management of drugs at the same level.

Article 23 The quality of drugs must comply with a national, provincial, autonomous regional or municipal standard.

"The Pharmacopoeia of the People's Republic of China" and drug standards promulgated by the Ministry of Public Health are national drug standards.

The Commission of Pharmacopoeia subordinate to the Ministry of Public Health is responsible for the stipulation and revision of national drug standards.

Article 24 The Ministry of Public Health and the health bureau of province, autonomous region or municipality may establish a Committee of Drug Evaluation for the evaluation of new drugs and the re-evaluation of drugs on sale.

Article 25 The Ministry of Public Health should launch an investigation of drugs approved for production; the approved documentary number of a drug should be revoked if the efficacy is not confirmed, if the adverse reaction is found to be serious, or if the drug is otherwise found to be hazardous to the health of the people.

The production and sale of a drug should not be continued if its approved documentary number has been revoked; those already produced should be destroyed or disposed under the supervision of the local health administrative agency.

Article 26 The importation of a drug is prohibited if the efficacy is not confirmed, if the adverse reaction is found to be serious, or if it is otherwise found to be hazardous to the health of the people.

Article 27 The signing of a contract for the importation of a drug which has not been imported previously should be approved by the Ministry of Public Health. An application for the importation of the drug should be accompanied

with the package insert, relevant information such as quality standard and control procedure, a sample of suitable size and a certification of the exporting country (or locality).

Article 28 Drugs to be imported should be examined by drug control institutions duly authorized by the Ministry of Public Health. The importation of a drug will not be approved unless it is found to be up to standard.

The importation of a small number of drugs to meet the urgent clinical needs of a medical unit or for personal self-medication should follow the formalities of the Customs.

Article 29 The Ministry of Public Health has the authority to restrict or prohibit the exportation of herbal drugs and their preparations if they are in short supply in the domestic market.

Article 30 The importation or exportation of narcotic drugs and psychotropic substances falling into the scope determined by the Ministry of Public Health is not allowed unless the importer or exporter is the holder of an "import license" or "export license" issued by the Ministry of Public Health.

Article 31 The sale of herbal drugs newly discovered or introduced from abroad is not allowed unless it is approved by the health bureau of province, autonomous region or municipality.

Article 32 Detailed provisions for the control of folk

medicines in certain regions will be stipulated by the Ministry of Public Health.

Article 33 The production and sale of bogus drugs are prohibited. A drug is deemed to be bogus if one of the following criteria exists:

1) The name of its ingredients shown on the label is different from the official designation used in the national, provincial, autonomous regional or municipal drug standard for the same substance.

2) It is not the same drug which is claimed by its name, or in reality it is not a drug at all.

Drugs falling into one of the following categories will also be subject to the same handling as bogus drugs:

1) The use has been prohibited by the Ministry of Public Health.

2) The production has not been approved.

3) Deteriorated,

4) Contaminated.

Article 34 The production and sale of drugs of inferior quality is prohibited. A drug is deemed to be of inferior quality if one of the following criteria exists:

1) The content of its ingredients does not comply with that which is specified in the national, provincial, autonomous regional or municipal drug standard.

2) The date of expiration is exceeded.

3) Non-compliance with drug standards in any other aspects.

Article 35 Personnel of drug manufacturing enterprises, drug handling enterprises and medical units in direct contact with drugs must undergo a medical examination annually. People suffering from communicable diseases or any other diseases, which may cause the contamination of drugs should not be engaged in any work that cannot avoid direct contact with drugs.

CHAPTER Ⅵ
THE PACKAGING AND REPACKAGING OF DRUGS

Article 36 Drugs should be packaged in a way to meet the requirements raised by the nature of individual drug, to facilitate their storage, transportation and medical usage. A date of expiration should be put on the package whenever such a date has been fixed.

Herbal drugs must be packaged in the course of transportation, each package should give the identity and origin of the consignment, date of dispatch, name of the consignor, and bear a sign showing that the quality of the consignment is acceptable.

Article 37 All the packages of a drug should be labelled

and a package insert should be attached to each package.

The label or package insert should give the name and strength of the product, name of the manufacturer, the serial number of the approval document, the lot number, principal ingredients, indications, usage, dosage, contra-indications, adverse reactions and precautions.

The label of narcotic drugs, psychotropic substances, poisons, radioactive pharmaceuticals and drugs for external use only should bear a sign of special device.

Article 38 A drug handling enterprise engaged in the repackaging of drugs should be equipped with the requisite facilities adaptable to the scale of its business, and the hygienic requirements should also be observed. Pharmaceutical technicians should be put in charge of the operation and the data of repackaging should be recorded completely and accurately.

A package insert should be attached to each package of the repackaged product. The label of the new package should give the name and strength of the product, name of the manufacturer, the lot number of the original package, name of the repackaging unit and the lot number of the repackaged product, and a date of expiration should also be put on the new package if the original package bears such a date.

CHAPTER Ⅶ
DRUGS UNDER SPECIAL CONTROL

Article 39 The State imposes special control upon narcotic drugs, psychotropic substances, poisons and radioactive pharmaceuticals. Regulations with respect to the control of such drugs will be stipulated by the State Council.

Article 40 The production of narcotic drugs, including their crude plants, should only be undertaken by those units jointly assigned by the Ministry of Public Health and other authorities concerned. Narcotic drugs should only be distributed by those units jointly assigned by the health bureau of province, autonomous region or municipality and other authorities concerned.

CHAPTER Ⅷ
THE CONTROL OF THE TRADEMARK AND ADVERTISEMENT OF DRUGS

Article 41 A registered trademark should be used for all drugs except herbal drugs and the prepared slice of herbal drugs. The sale of drugs without a registered trademark is prohibited.

The registered trademark should be put on the package and label of the drug.

Article 42 The advertisement of a drug must be approved by the health bureau of province, autonomous region or municipality. It is not allowed to publish, broadcast, disseminate or poster without approval.

Article 43 An application for the advertising of a drug in this country submitted by a foreign enterprise should be accompanied with a certification issued by the country (or locality) of its production, the package insert and relevant information.

Article 44 The text of the advertisement of a drug should be consistent with that of the package insert approved by the Ministry of Public Health or the health bureau of province, autonomous region or municipality.

CHAPTER Ⅸ
THE SUPERVISION OF DRUGS

Article 45 Health bureaus above the county level are responsible for the supervision of drugs.

Drug administrative agencies and drug control institutions subordinate to the health bureau above the county level may be established.

Article 46 Drug inspectors should be appointed by the health bureau above the county level. They should be selected from pharmaceutical technicians. A certificate will

be issued to them by government at the same level.

Article 47 Drug inspectors are authorized to supervise and inspect the quality of drugs produced, handled or used by drug manufacturing enterprises, drug handling enterprises and medical units under their jurisdiction. If necessary, they may take samples or ask for information from the relevant units in compliance with the stipulation. Their requests must be fully satisfied, it is not allowed to keep anything back from them. Drug inspectors are obliged to keep the technical information provided by drug manufacturing enterprises or scientific research units confidential.

Article 48 Drug manufacturing enterprises, drug handling enterprises and medical units should conduct regular studies on the quality, efficacy and adverse reaction of drugs produced, handled or used.

Medical units should submit a report immediately to the local health bureau in case drug poisoning has occurred.

Article 49 The drug control department or personnel of drug manufacturing enterprises and drug handling enterprises should accept the vocational guidance from the local drug control institution.

CHAPTER X
LEGAL OBLIGATIONS

Article 50 In the case of manufacturing or selling bogus drugs, the bogus drugs should be seized, the illicit income confiscated and a fine imposed. In some cases all the activities of the enterprise should be suspended until it has been consolidated, or its "drug manufacturer certificate", "drug handler certificate" or "drug dispensing certificate" should be revoked.

The penal liability of the person or enterprise directly responsible for the production or sale of bogus drugs to endanger people's health should be sought pursuant to article 164 of the Penal Code.

Article 51 In the case of manufacturing or selling drugs of inferior quality, the drugs should be seized and the illicit income confiscated, with or without a penalty. If the offence is serious, all the activities of the enterprise should be suspended until it is consolidated or its "drug manufacturer certificate", "drug handler certificate" or "drug dispensing certificate" should be revoked.

The penal liability of the person or enterprise directly responsible for the production or sale of drugs of inferior quality to endanger people's health and create serious con-

sequence should be sought pursuant to article 164 of the Penal Code.

Article 52 In case of manufacturing, handling or dispensing drugs without a "drug manufacturer certificate", "drug handler certificate" or "drug dispensing certificate", the operation of the unit should be suspended. All the drugs so produced, handled or dispensed and the illicit income should be confiscated, with or without a penalty.

Article 53 In the case of violating any other provisions of this Law with respect to the management of drug production and drug handling, a warning should be issued or a fine imposed.

Article 54 The decision of an administrative penalty pursuant to this Law should be made by the health bureau above the county level. In the case of an offence against article 15 of this Law or the provisions of chapter Ⅶ of this Law with respect to the advertising of drugs, the decision of an administrative penalty should be made by the industrial and commercial management agency.

An order to impose a penalty on a drug manufacturing enterprise or drug handling enterprise directly under the jurisdiction of the central, provincial, autonomous regional or municipal People's Government which consists of the suspension of its operation for seven days or more, or the revocation of its "drug manufacturer certificate" or "drug

handler certificate" should be submitted by the health bureau of province. autonomous region or municipality to the People's Government at the same level for final decision.

An order to impose a penalty on a drug manufacturing enterprise or drug handling enterprise under the jurisdiction of the People's Government at or below the city and county level which consists of the suspension of its operation for seven days or more, or the revocation of its "drug manufacturer certificate" or "drug handler certificate" should be submitted by the health bureau of cities or counties to the People's Government at the same level for final decision.

Drugs confiscated should be disposed under the supervision of health administrative agencies.

Article 55 Any objection to the decision of an administrative penalty should be referred to the People's Court within a period of 15 days counting from the date of notification of the penalty. However, the decision involving the control of drugs should be enforced immediately. In case the decision has not been enforced and the time limit for an appeal has elapsed, the People's Court shall order its compulsory execution at the request of the organization who has made such a decision.

Article 56 In the case of drug poisoning due to an offence against this Law, the group or person causing the damage are liable to make compensation for the loss. The victim has

the right to make an appeal to the health bureau above the county level for compensation; in the event of a dispute, the party concerned may bring the case to the People's Court. The victim may also make an appeal directly to the People's Court.

An appeal for compensation must be submitted within a period of one year counting from the date on which the victim or his advocate became aware or ought to have been aware of the injury, the appeal will not be entertained beyond this time limit.

CHAPTER Ⅺ
SUPPLEMENTARY PROVISIONS

Article 57 The terms used in this Law are defined as follows:

Drugs: refer to those substances used for the prevention, treatment and diagnosis of human diseases, and for the intentional regulation of human physiological functions, for which indications, usage and dosage have been established, including herbal drugs and their preparations, prepared slice of herbal drugs, chemical drugs and their preparations, antibiotics, biochemical drugs, radioactive pharmaceuticals, sera and vaccines, blood products, diagnostic aids etc.

New drugs: refer to those drugs which have never been

produced in this country.

Excipients: refer to the vehicles and additives used for the production and dispensing of drugs.

Drug manufacturing enterprises: refer to those enterprises exclusively or partly engaged in the production of drugs.

Drug handling enterprises: refer to those enterprises exclusively or partly engaged in the handling of drugs.

Article 58 The production of drugs referred to in this Law does not include the cultivation and collection of medicinal plants and the breeding of medicinal animals.

Article 59 Measures for the enforcing of this Law should be stipulated by the Ministry of Public Health and submitted to the State Council for approval.

Provisions for the management of military remedies will be stipulated by the competent authorities of the People's Liberation Army of China.

Article 60 This Law shall come into force on July 1, 1985.

-Translated by the Bureau of Drug Administration and Policy of the Ministry of Public Health. In case of discrepancy, the original version in Chinese shall prevail.-